K063438

JAN 17 2007

Summary of Safety and Effectiveness

Applicant/consultant: Brauer Device Consultants LLC
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Rockville, Maryland 20850
Phone: 301-545-1990
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Contact: Christine L. Brauer, Ph.D.

Manufacturer/Submitter: Tecres S.p.A.
Via Andrea Doria, 6
37066 Sommacampagna
Verona - Italy
FDA owner/operator ID #: 9033624

Date: November 14, 2006

Trade/Proprietary name:	Vspspn
Common name:	Acrylic Resin
Regulation number:	888.3027
Device class:	II
Classification panel:	Orthopedic
Classification Product Code:	NDN, LOD

Intended Use:
Vspspn is indicated for the treatment of pathological fractures of the vertebral body.

Predicate Device Information
The predicate device is Mendec Spine (K042415) and, for the packaging, Visioplast (#K042414).

Device Description
Vspspn is a two-part (powder and liquid) radiopaque, polymethyl methacrylate acrylic resin. The powder and liquid components are mixed together at the point of use to form the resin. The product is supplied sterile, for single use.

Summary of Safety and Effectiveness

Substantial Equivalence

Vspspn is substantially equivalent to the predicate Mendec Spine (K042415) since they have the same design, incorporate the same materials, have the same performance and mechanical characteristics, have the same shelf life and equivalent packaging, and are sterilized by the same method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tecres SPA
% Christine Brauer, Ph.D.
Brauer Device Consultants, LLC
1700 Research Boulevard
Rockville, Maryland 20850

JAN 17 2007

Re: K063438
Trade/Device Name: VSPSPN
Regulation Number: 21 CFR 888.3027
Regulation Name: Cement, bone, vertobroplasty
Regulatory Class: Class II
Product Code: NDN
Dated: November 14, 2006
Received: November 15, 2006

Dear Dr. Brauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bucher
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063438

Device Name: Vspspn

Indications For Use:

Vspspn is indicated for the treatment of pathological fractures of the vertebral body using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063438